

Experiment Number: A83804

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Mouse/CD-1

**G04: In Vivo Micronucleus Summary Data**

Test Compound: AZT+3TC+NVP combination

CAS Number: AZT3TCCOMBO

Date Report Requested: 09/21/2018

Time Report Requested: 07:05:59

**NTP Study Number:**

A83804

**Study Duration:**

8 Days

**Study Methodology:**

Slide Scoring

**Male Study Result:**

Positive

Experiment Number: A83804  
Test Type: Genetic Toxicology - Micronucleus  
Route: Gavage  
Species/Strain: Mouse/CD-1

**G04: In Vivo Micronucleus Summary Data**  
Test Compound: AZT+3TC+NVP combination  
CAS Number: AZT3TCCOMBO

Date Report Requested: 09/21/2018  
Time Report Requested: 07:05:59

---

Tissue: Blood; Sex: Male; Number of Treatments: 0; Time interval between final treatment and cell sampling: 24 h

---

| Dose (mg/kg)                 | N | MN PCE/1000    | p-Value   | % PCE        |
|------------------------------|---|----------------|-----------|--------------|
|                              |   | Mean ± SEM     |           | Mean ± SEM   |
| Vehicle Control <sup>1</sup> | 5 | 2.60 ± 0.53    |           | 38.10 ± 6.28 |
| 1.0                          | 5 | 128.00 ± 29.74 | < 0.001 * | 21.40 ± 2.64 |
| 2.0                          | 5 | 195.20 ± 15.94 | < 0.001 * | 31.20 ± 3.50 |
| 3.0                          | 5 | 203.70 ± 31.32 | < 0.001 * | 27.20 ± 4.16 |
| Trend p-Value                |   | < 0.001 *      |           |              |

---

Trial Summary: Positive

---

Experiment Number: A83804  
Test Type: Genetic Toxicology - Micronucleus  
Route: Gavage  
Species/Strain: Mouse/CD-1

**G04: In Vivo Micronucleus Summary Data**  
Test Compound: AZT+3TC+NVP combination  
CAS Number: AZT3TCCOMBO

Date Report Requested: 09/21/2018  
Time Report Requested: 07:05:59

#### LEGEND

---

MN = micronucleated, PCE = polychromatic erythrocyte, NCE = normochromatic erythrocyte

CAS Number = Chemical Abstracts Service registry number

N = Number of subjects

Values given as Mean or Mean  $\pm$  Standard Error Mean

Results were tabulated as the mean of the pooled results from all animals within a treatment group, plus or minus the standard error of the mean

Pairwise comparison to the concurrent control, dosed groups significant at  $p = 0.025$ /number of treatment groups; positive control value is significant at  $p = 0.05$

Cochran-Armitage trend test, significant at  $p = 0.025$

\* Statistically significant pairwise or trend test

1: Vehicle Control: 0.2% Methylcellulose and 0.1% Tween 80 in water

**\*\* END OF REPORT \*\***